

REMARKS

Amendment

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Election/Restrictions

Applicant hereby affirms the election of claims 1-13 for examination.

The 35 U.S.C. §102 Rejection

Claims 1-13 were rejected under 35 U.S.C. §102(b) as being anticipated by **Herndon et al.** The rejection is respectfully traversed.

Claims 1 and 9 have been amended to more particularly point out and distinctly claim that which the Applicant considers to

be the invention. To this end, claims 1 and 9 have been amended to recite methods of using a beta-adrenergic antagonist generally or propranolol specifically to decrease muscle protein catabolism in an individual having a severe burn. Using stable isotope methodology and serial body composition scanning, the present invention demonstrates for the first time that β -adrenergic blockade with propranolol diminishes skeletal muscle protein wasting seen after severe burn (Applicantion's specification and Figure 2 and Table 3). Out of twenty-five severely burned children studied, thirteen were safely given propranolol and experienced a decrease in resting energy expenditure. Twelve severely burned children had an improved net muscle protein balance. With long-term β -adrenergic blockade, this translated into greater lean body mass.

In contrast, **Herndon** et al. taught "selective $\beta 1$ -adrenergic and nonselective adrenergic receptor blocking agents can significantly reduce heart rate and myocardial oxygen consumption in hypermetabolic burned patients without adversely affecting protein kinetics" (page 1304, left column, last paragraph). **Herndon** et al. did not teach or suggest that a beta-adrenergic antagonist

generally or that propranolol specifically can decrease muscle protein catabolism in burned patients as claimed herein.

Furthermore, **Herndon** et al. actually teach away from the present invention because **Herndon** et al. concluded that beta-adrenergic antagonist or propranolol had no effect on muscle protein metabolism in burned patients. **Herndon** did not "document an effect of propranolol and metoprolol on protein kinetics..... The fact that neither of these techniques revealed any significant effect of either agent on protein kinetics indicates that the effect is of minimal clinical concern" (page 1304, left column, second paragraph).

In view of the above remarks, **Herndon** et al. did not teach or suggest each and every aspect of the instant invention. Instead, **Herndon** et al. teach away from the present invention. Hence, **Herndon** et al. did not anticipate claims 1 and 9 of the instant application. Accordingly, Applicant respectfully requests that the rejection of claims 1-13 under 35 U.S.C. §102(b) be withdrawn.

This is intended to be a complete response to the Office Action mailed January 3, 2002. If any issues remain outstanding, the

Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

Date: March 7, 2002



Benjamin Aaron Adler, Ph.D., J.D.
Registration No. 35,423
Counsel for Applicant

ADLER & ASSOCIATES
8011 Candle Lane
Houston, Texas 77071
(713) 270-5391
badler1@houston.rr.com

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 1 has been amended as follows:

1. (amended) A method of decreasing muscle protein catabolism in treating an individual having a severe burn, comprising the step of administering to said individual a pharmacologically effective dose of a beta-adrenergic antagonist.

Claim 7 has been amended as follows:

7. (amended) The method of claim 6 †, wherein said propranolol is administered intraveneously in a dose of about 1 mg/kg of the body.

Claim 9 has been amended as follows:

9. (amended) A method of decreasing muscle protein catabolism in treating an individual having a severe burn, comprising the step of administering to said individual a pharmacologically effective dose of propranolol.